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June 15, 2017

Honorable Richard J. Sullivan  
United States District Judge  
United States Courthouse  
500 Pearl Street  
New York, New York 10007

Re: United States ex rel. Susan Vierczhalek, MD, et al. v. MedImmune Inc., et al. and  
The State of New York v. MedImmune, Inc., 09-cv-3919 (RJS)

Dear Judge Sullivan,

Plaintiff the State of New York (the "State") and Defendant MedImmune LLC (formerly known as MedImmune Inc., "MedImmune") (together, the "Parties") respectfully submit this Joint Letter and proposed Civil Case Management Plan and Scheduling Order, pursuant to this Court's Order dated April 20, 2017 (ECF No. 57). The initial conference is scheduled for June 23, 2017, at 9:30 a.m. The State is ready to appear on the scheduled date. MedImmune is also prepared to appear on the scheduled date. However, yesterday Relator notified the Court of her intention to proceed with the federal qui tam action and requested that her Complaint be unsealed for Service on MedImmune. MedImmune has not seen Relator's allegations against it, but may request leave of the Court to file a motion to dismiss that Complaint. MedImmune respectfully submits that, for the sake of efficiency, it would be best to postpone the conference until MedImmune has an opportunity to evaluate the Complaint and for all of the parties, including Relator, to participate in discussions regarding scheduling.

**(1) Nature of the Action:**

The State's Allegations: The State of New York (the "State") has intervened against Defendant MedImmune, the manufacturer of Synagis (Palivizumab). The State seeks to recover treble damages and civil penalties under the New York State False Claims Act, N.Y. State Finance Law §§ 187-190, damages and other monetary relief under N.Y. Social Services Law § 145-b, N.Y. Executive Law § 63(12), N.Y. Executive Law § 63-c, and to recover amounts by which MedImmune was unjustly enriched.

The State seeks to recover from MedImmune millions of dollars in damages incurred by the NYS Medical Assistance Program ("Medicaid") based on the State's allegations of MedImmune's providing improper remuneration to Medicaid provider Trinity Homecare LLC,

which was acquired by successor parents (“Trinity”) concerning Synagis for the period January 2007 through March 2011. In July 2015, the Court so-ordered a Stipulation and Order of Settlement with Trinity for \$22.4 million. This was a negotiated amount and the State is also entitled to recover double and treble damages, as well as penalties, from MedImmune before any offset or credit is made for compensatory payments. (See N.Y. State Fin. Law § 194, Chapter IX, Part 400.6 – Application of the damage multiplier).

The State’s complaint alleges that by providing kickbacks to Trinity, through several forms of remuneration, MedImmune knowingly caused the presentment of false Synagis claims for payment to Medicaid by Trinity for more than 600 babies. MedImmune’s illegal conduct included: a) obtaining and providing valuable infant patient leads to Trinity from NICU logbooks; b) obtaining and providing leads and/or referrals to Trinity from licensed medical professionals; and c) providing personnel assistance and protected health information (“PHI”) to Trinity to try to obtain initial Synagis prescriptions and thereafter, consent for refills.

MedImmune’s Defenses: As a matter of law, the State has failed to plead a valid statutory or common law cause of action pursuant to Rules 12(b)(6) and 9(b). The State’s related remaining claims also fail. More specifically, MedImmune contends that the State has failed to plead any of the following with plausibility or particularity: (a) an actionable kickback under the federal or state anti-kickback statute; (b) actionable falsity of any kind; (c) materiality within the meaning of *Universal Health Services v. Escobar*, 136 S. Ct. 1989 (2016); and (d) viable causes of action under any of the state law counts. In addition, the State may have already recovered for claims from Trinity, thereby barring a double-recovery from MedImmune.

## **(2) Jurisdiction and Venue Lie in This Court:**

This Court has subject matter jurisdiction over the original action filed by Relator under 28 U.S.C. §§ 1331 and 1345, and pursuant to 31 U.S.C. § 3732(b) because the action arises from the same alleged transaction or occurrence as an action brought under 31 U.S.C. § 3730.

Pursuant to 31 U.S.C. § 3732(b), the Court has jurisdiction over the State law claims for the recovery of funds paid by a State because the State’s allegations arise from the same transaction or occurrence as the action brought by the relator under § 3730. The Court also has the authority to exercise supplemental jurisdiction over the state statutory, common law, and equitable causes of action pursuant to 28 U.S.C. § 1367(a). Federal district courts have supplemental jurisdiction over state law claims that “are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy.” 28 U.S.C. § 1367(a). Further, the Court has already asserted jurisdiction in this matter as it oversaw the settlement with former Defendant Trinity.

The State alleges that the Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332(c) because the matter in controversy exceeds the sum or value of \$75,000 and the parties are citizens of different states and that there is complete diversity. MedImmune asserts that, because the State is not a citizen for purposes of diversity, this is not a basis for the Court’s jurisdiction.

Venue is proper in the Southern District of New York pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because MedImmune does business in this District and the State alleges that false or fraudulent acts occurred in this District.

## **(3) Outstanding Motion and/or Requests to File a Motion:**

On June 5, 2017, MedImmune filed a letter brief with this Court requesting leave to file a

pre-answer motion to dismiss the State's Complaint. The State filed its response on June 8, 2017.

**(4) Discovery that has Taken Place and Discovery that Is Necessary for The Parties to Engage in Settlement Negotiations:**

The State's Response: The State believes that MedImmune has more than enough information about its own conduct to engage in settlement negotiations now. MedImmune has also been served with the State's detailed complaint, as of March 31, 2017, which contains a detailed list reflecting baby identification number of Medicaid claims, dates, dollar value paid, and quantity of Synagis claimed for, all organized by hospital location, or by reference to Trinity's internal pharmacy notes (clinical or CPR notes) that identifies the particular false claims resulting from MedImmune's conduct.

MedImmune's Response: The Relator's case was initially filed in 2009. The State served subpoenas in 2011 and MedImmune has made substantial productions to the State over a number of years, which has included the production of over 120 gigabytes of data. The State also has been able to interview or depose multiple witnesses, but MedImmune has not had an opportunity to take any discovery from the State. As MedImmune has repeatedly stated in its discussions and correspondence with the State, it cannot engage in meaningful settlement negotiations without having access to the State's Medicaid claims data, so that—at minimum—MedImmune can verify the State's assertion that the alleged claims were paid, and can have a fair opportunity to understand and test the State's damages methodology.<sup>1</sup> The State has acknowledged that this data is discoverable, but refuses to produce it for purposes of facilitating settlement discussions. MedImmune cannot simply accept the State's allegations at face value, and should not be required to negotiate blindly without the benefit of the discoverable information that forms the basis for the State's damage claims. Absent this information, MedImmune cannot fairly test the validity of the State's asserted damages—or even confirm that the claims occurred—and cannot ascertain the extent to which the State may have already been compensated for those claims through the Trinity settlement.

**(5) Prior Settlement Discussions:**

**Settlement Discussions with MedImmune's Prior Counsel:**

July 23, 2015 - State requested a meeting with MedImmune's prior counsel of 4 years, most recently associated with Sheppard Mullin to discuss its findings to date and possible settlement.

July 29, 2015 - Counsel responded that they were "very interested in meeting to discuss a resolution."

August 20, 2015 – State made presentation to counsel and in-house counsel. Settlement demand made and response requested by September 4.

**Settlement Discussions with MedImmune's Current Counsel:**

September 24, 2015 - Informed by John C. Dodds of Morgan, Lewis & Bockius LLP that his firm would represent MedImmune, and prior counsel was no longer involved.

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<sup>1</sup> While MedImmune retained an expert, who may assist with settlement discussions, the expert cannot meaningfully assist without having access to claims data, which should include information about patients, dates of birth, and prescribers. However, the State has not provided such data or how the identified 600 patients were selected.

October 15, 2015 - State presented its findings to Mr. Dodds and Matthew J.D. Hogan of Morgan Lewis and in-house counsel also attended. This meeting lasted a total of approximately one and a half hours.

October 27, 2015 – Counter-offer made. MedImmune explained it could not make a more significant offer without further information supporting the State's allegations. The State believed it had provided material information including information about its damages and requested a realistic counter-offer.

December 7, 2016 - State informed counsel State was intending to intervene and file complaint.

December 15, 2016 - Counsel contacted State to discuss State's settlement demand and next steps.

December 16, 2016 - MedImmune and State entered into tolling agreement for the period December 16, 2016 through March 14, 2017.

December 21, 2016 - State contacted counsel, requesting response to State's lowered demand based on prior information provided. MedImmune asserts that the demand was decreased only nominally.

January 4, 2017 - Counsel offered to make a presentation to State contingent on a State supervisor being present. State informed counsel that attorneys assigned to the matter were authorized to meet with counsel and that a supervisor was not required to attend.

February 6, 2017 - State contacted counsel to follow-up on its offer for MedImmune to make a presentation and proposed dates.

February 10, 2017 - Counsel again requests supervisor to attend presentation, in light of the fact that the parties were at an impasse because they had divergent views of the case. Counsel also responded, asking the State to reduce demand. Counsel stated, "unless you are willing to significantly reduce your demand of [], we do not think that we will make meaningful progress toward a resolution to this matter." State asserts that Counsel provided no reason for State to lower its demand.

February 28, 2017 - Counsel made presentation to State with State supervisor present. In-house counsel for MedImmune was also present. Counsel for MedImmune suggested that, even though MedImmune believed the State's theory of liability to be invalid, the Parties could explore the possibility of settlement based solely on the issue of damages. To this end, counsel for MedImmune requested that the State provide additional information about damages beyond what was conveyed in State's October 2015 presentation. The State initially agreed to do so, but then chose not to provide any additional information before filing its complaint because the Court declined to extend the State's time to file (on March 15, 2017). The State asserted that the Complaint would provide MedImmune with more information than the State had offered to provide in its discussions with Counsel.

March 13, 2017 - MedImmune and State entered into amended tolling agreement through March 31, 2017.

March 28, 2017 - Counsel again requested information as to State's damages for purposes of settlement discussions.

March 29, 2017 - State informed Counsel that complaint due to be filed by March 31, 2017 would provide counsel with necessary information.

March 31, 2017 – State filed complaint containing information as to damages including a chart (Exhibit C), which the State asserts reflects Medicaid paid claim amounts and related information for approximately 600 patients, whom the State identified by number. MedImmune



asserts that nothing in that exhibit explains what alleged remuneration is associated with each patient. The State asserts that Exhibit C should be read in conjunction with the Complaint allegations that describe the conduct. Counsel later offered to enter into a HIPAA-qualified protective order so that the State could provide Medicaid claims data, but the State declined.

April 17, 2017 - Counsel sent another letter to State requesting claims data. State notes that counsel did not comment on substantive allegations or information contained in Exhibit C chart. MedImmune notes that the allegations were what the State had previously conveyed and Exhibit C did not provide sufficient information to analyze the State's alleged damages.

April 26, 2017 - State asked counsel how requested claims data would advance settlement negotiations when State's claims are based on evidence of MedImmune providing remuneration to Trinity which is not documented in Medicaid claims.

May 15, 2017 - Counsel again requested Medicaid claims data and did not respond to State's questions, asserting that if the parties are to discuss a settlement, it requires some level of transparency regarding data that will be discoverable in any event.

May 31, 2017 - State explained damages methodology and asked counsel to explain why it needed further data and what it would do with it. Counsel agreed to speak with its expert to see what Medicaid claims data it thought would be helpful. The State offered to identify what relevant data fields exist in the claims data. No resolution obtained as of yet about the data request, but State is amenable to further discussions as to what sample or HIPAA redacted data would be helpful without engaging in full blown discovery for settlement purposes.

**(6) Estimated Length of Trial:**

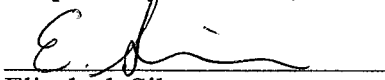
The State estimates a trial length of approximately two and a half weeks. MedImmune estimates a trial length of approximately two weeks.


**(7) Additional Information The Court May Need in Resolving This Action:**

The State's Response: The State continues to be receptive to resolving this matter with MedImmune. We welcome a realistic counter-offer to our demand of December 2016. State's damages may increase due to further investigation.

MedImmune's Response: MedImmune has been and remains willing to engage in good faith settlement negotiations, but cannot meaningfully respond to the State's demand without having access to clearly discoverable information, including (a) Medicaid claims data for Synagis, (b) information regarding what remuneration from MedImmune the State alleges is associated with each claim, and (c) information regarding which claims were resolved in the State's settlement with Trinity and whether those are the same claims at issue in this case.

Respectfully submitted,

  
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